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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,134	02/12/2007	Deborah A. Yurgelun-Todd	04843/112002	5991

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EXAMINER	
KOSAR, AARON J	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
03/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/556,134	YURGELUN-TODD ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment and argument filed November 4, 2009 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection of record not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 4 and 5. Claims 1-3, 6, and 7 are pending and have been examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Boismenu et al (U.S. Patent Application Publication No. 2005/0002922).

A method of ameliorating bipolar disorder in an individual in need thereof comprising administering to the individual an amount sufficient to ameliorate the bipolar disorder in said

individual, is claimed. The dependent claims further recite intravenous, bolus infusion and administering a species of medication.

Boismenu et al anticipates the claims by teaching a method of treating an affective disorder of a patient by administering an effective dosage of secretin to said patient (whole document, e.g. claim 1). The affective disorder comprises bipolar disorder (e.g. claim 4) and the administering comprises intermittent, interval and/or intravenous administrating (intravenous bolus infusion, e.g. claims 11-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1-3 are rejected under 35 U.S.C. 103(a) as being obvious over by Boismenu et al (U.S. Patent Application Publication No. 2005/0002922).

Boismenu teaches administering secretin to a patient, including intravenously (claim 2) and in a unit amount of a daily dosage of 0.04, 0.5, 1, 3, 10, 30, and 100 μg/kg (0.02, 0.25, 0.5, 1.5, 3, 15, and 50 CU/kg).

Boismenu does not expressly recite in a single preferred embodiment administering of 2CU/kg (4 μg/kg) secretin.

It would have been obvious to a person of ordinary skill in the art at the time the instant invention was made to have administered 4 μg/kg (2CU/kg) secretin in the method of Boismenu, because Boismenu teaches administering secretin to reduce symptoms in individuals in need thereof including in bipolar disorder individuals, providing a dose of 4 μg/kg (e.g. pgh.153-154),. Boismenu is relied upon for the reasons discussed above. If not expressly taught by Boismenu, based upon the overall beneficial teaching provided by this reference with respect to dosage amounts in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable dosage/concentration ranges in which to perform such an administering to said individual in need thereof), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. (see also MPEP § 2144.05)

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-3, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boismenu et al (U.S. Patent Application Publication No. 2005/0002922) as applied to claims 1-3 above, and further in view of Renshaw (U.S. Patent Application Publication No. 2002/0019364).

Boismenu and the claims are as above. Boismenu further teaches administering secretin alone or in combination with other medications (pgh.10) and the various symptoms of bipolar disorder (see whole document, e.g pgh. 62-69).

Boismenu does not recite is a single preferred embodiment the combination of an antidepressant, anticonvulsant, antianxiety, antimanic, antipsychotic, antiobsessional, sedative-hypnotic, stimulant, or anti-hypertensive medication (herein "the medication" or the species thereof as in instant claim 7 (herein "the medication species").

Renshaw teaches medications known at the time of the instant invention as "antidepressant, anticonvulsant, antianxiety, antimanic, antipsychotic, antiobsessional, sedative-

hypnotic, stimulant, or anti-hypertensive medications", including the medication species as recited therein (see whole document, e.g. pgh. 66).

It would have been obvious to a person of ordinary skill in the art at the time the instant invention was made to have provided the medication or the medication species because Boismenu teaches treating the by administering secretin alone or in combination with additional medications. One would have been motivated to have provided in the method of Boismenu the medication or the medication species, because from the symptoms of bipolar disorder as taught by Boismenu and by Boismenu teaching administering secretin alone or in combination with other medications, a person of ordinary skill in the art would recognize from that the medications taught by Renshaw that said medications were known to be administered to an individual having these symptoms for the desired effect of as antidepressant, anticonvulsant, antianxiety, antimanic, antipsychotic, antiobsessional, sedative-hypnotic, stimulant, or anti-hypertensive medications. One would have had a reasonable expectation of success in providing the medications in the method of Boismenu because the method as-drafted does not require any special activity of the medications or species and thus merely require that the compounds be present and that said compounds function according to their known, inherent properties.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655